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Massachusetts State Laboratory Institute

Lab News

March 1993

Ralph J. Timperi, M.P.H., Assistant Commissioner for Laboratory and Environmental Sciences

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New England Regional Newborn Screening

The New England Regional Newborn Screening Program (NERNSP) tests filter paper blood samples from newborns born in Massachusetts, Maine, New Hampshire, Vermont, and Rhode Island for a variety of inborn errors, endocrine disorders, and infectious diseases. The NERNSP is operated in cooperation with the Massachusetts Department of Public Health, the Departments of Public Health of the New England States, and the Massachusetts Health Research Institute. The Program is funded through fees charged for testing services and Federal research contracts that support the ongoing development of new screening technology and epidemiologic studies.

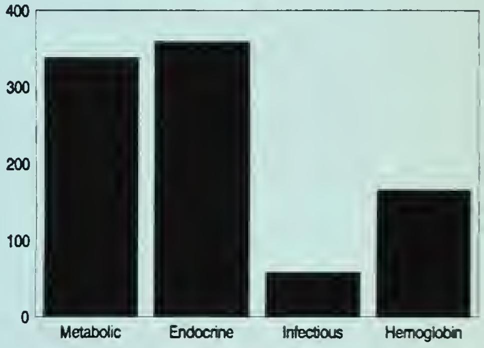
The NERNSP currently consists of four laboratory divisions: 1) Hemoglobinopathies — screening for sickle cell disease and clinically significant hemoglobin traits; 2) Endocrine disorders — screening for hypothyroidism and congenital adrenal hyperplasia; 3) Infectious disease screening for toxoplasmosis (and possibly for other diseases as treatment becomes available); and 4) Metabolic disorders — screening for galactosemia, maple syrup urine disease, homocystin-uria, and phenylketonuria. These disorders are treatable with the potential of preventing a lifetime of disability or death.

The NERNSP is currently testing approximately 150,000 samples annually from five New England States for as many as eight disorders.

The frequency of each disorder ranges from one per thousand to one per 150,000.

To help assure immediate care and treatment, the NERNSP has a staff of on site physicians who coordinate follow up and patient management with the newborn's primary care physician. Since inception in 1962, the Program has identified more than 900 newborns with life threatening disorders.

New England Regional Newborn Screening Program
Disorders Detected
Massachusetts Data



1962-1993

To obtain additional information about the NERNSP or a brochure describing their services in greater detail, please call the New England Regional Newborn Screening program at (617) 522-3700, extension 165.

305 South Street, Boston, Massachusetts 02130

Editorial Notes...

Notes on a CLIA '88 Inspection

Harvey George Ph.D., Director of Diagnostic Laboratories

The Massachusetts State Laboratory Institute, a Public Health facility that receives and tests approximately 1,000,000 specimens per year, recently received a five day unannounced inspection (January 25-29, 1993) by three regional inspectors for the Health Care Financing Administration (HCFA).

The inspection, in keeping with current trends in accreditation and certification, was outcome oriented and stressed Total Quality Management Procedures. Procedure manuals were not the point of focus, rather they served as review or documentation records when procedural questions arose. The focus point was randomly selected patient requisitions. Written documentation by every individual involved in the testing process was sought. It was not sufficient to be able to demonstrate the performance of quality control, but a system of regular review and interpretation by the supervisor (identification of shifts, trends, etc.) of quality control records was required. The surveyors requested evidence that all levels of testing personnel understood and were involved in the quality assurance process.

Emphasis was placed on developing systems for quality assurance and a total quality management approach to laboratory operations. All complaints, incidents and problems must be documented, reviewed and corrective actions outlined and documented.

Adequate documentation is paramount to compliance. It was pointed out that formal training for both new employees, as well as experienced personnel being cross trained, must be documented. This training must encompass specific areas identified in the regulations, and it is the responsibility of the laboratory director to ensure this process and sign off on records on an annual basis.

Continual self-monitoring and planned focused improvement was the overriding theme of the inspection.

LAB NEWS is published quarterly by the staff of the Massachusetts State Laboratory Institute, 305 South St., Boston MA 02130 (Tel. 617-522-3700). Complimentary subscriptions are available upon request, as are back issues as long as supplies last. LABNEWS: *Editor,* Garry R. Greer; *Editorial Board:* Ralph J. Timperi, M.P.H., *Assistant Commissioner for Laboratory and Environmental Sciences,* Harvey George Ph.D., *Director of Diagnostic Laboratories*

Pertussis Update

The dramatic increase in the number of reported Pertussis cases from 20 in 1984 to more than 300 in 1992 has underscored the need for age-appropriate immunization of all Massachusetts children. It has also stressed the importance of treatment or prophylaxis of cases and case contacts. The Department of Public Health, recently issued recommendations for patient management and outbreak control.

Epidemiologic data indicates that while clusters of unimmunized children account for significant morbidity, it is the waning immunity in adolescents and adults that currently accounts for most cases. Adolescents and adults account more than 70% of all cases. This older age group transmits the disease to the younger more vulnerable age groups and other high risk individuals.

Testing Available at the Massachusetts State Laboratory Institute:

The State Laboratory Institute currently offers both serological testing and culture identification as aids in the diagnosis of Pertussis. The choice of which test to obtain is a function of the duration of a patient's symptoms and immunization history.

Single Serum Specimen Testing:

A serologic test for Pertussis that can be performed on a single late acute or early convalescent serum specimen (obtained from a patient greater than 11 years of age, having a persistent cough for 2 - 8 weeks), has been available at the State Laboratory Institute for a number of years. This test, a quantitative ELISA procedure, measures the concentration of Bordetella pertussis antibody (IgG). A single specimen is uninterpretable in **immunized** patients less than 11 years of age.

Acute and Convalescent Sera Testing:

For those patients under 11 years of age who are **unimmunized** traditional serological testing, requiring a 4-fold rise in titer between acute and convalescent sera (blood drawn between 2-8 weeks from the onset of symptoms) must be performed.

For those patients under 11 years of age, who are immunized all serology results are considered uninterpretable; therefore serological specimens should not be submitted for this group.

Culture Testing:

Nasopharyngeal cultures should be obtained in patients whose symptoms have persisted for less than 2 weeks. Culture isolation of Bordetella pertussis requires the use of specialized transport and/or growth media, and biochemical confirmation. The rapid diagnostic test (flourescent antibody test), has been discontinued due to the unavailability of satisfactory commercial reagents.

The Massachusetts State Laboratory Institute provides two types of pertussis collection kits, one for culture/serology and one for serology only. Pediatric blood collection tubes are supplied in both kits; vacutainers (red top tubes) which can be used for older patients **are not**. Test kits are available to physicians and hospital laboratories upon request by calling (617) 522-3700, X243.

If you have any questions regarding Pertussis or have suspected cases to report, please contact your local Board of Health or the Immunization Program of the Massachusetts Department of Public Health at (617) 522-3700, X420.

Timing of Laboratory Specimens

Duration of cough	Type of Specimen
1. ≤ 14 days	Culture and Serum (0.5ml or more)
2. > 14 days	Serum* for Serology only (0.5ml or more)

* Serum may be sent in a red top tube if specimen collection kits are unavailable.

Mid-Atlantic Strain of Racoon Rabies Reaches Bay State

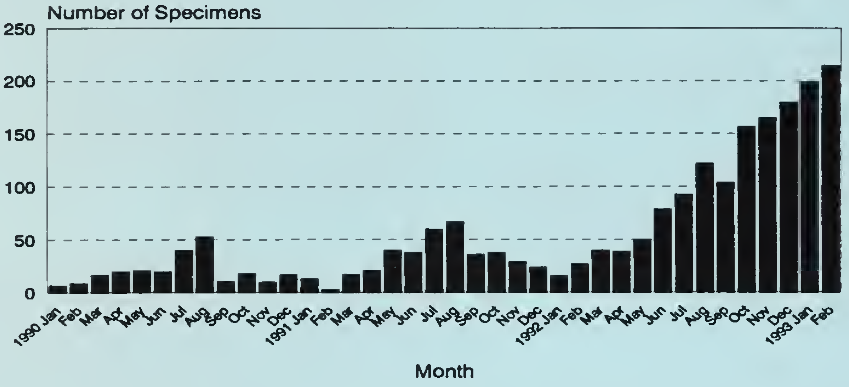
Since 1977, an outbreak of rabies in raccoons has been progressing from West Virginia northward through the mid-Atlantic states. The first raccoon with this mid-Atlantic raccoon strain of rabies virus was identified in Massachusetts on September 16 in Ashby.

Since then, the epizootic has spread to 37 other cities or towns, in the north-central, southwestern and recently the eastern part of the state (see map). Through the month of February the laboratory has identified 91 rabies positive animals associated with the outbreak; 85 raccoons, 3 skunks, 1 cat, 1 woodchuck and 1 red fox were virus positive.

Bat rabies, already endemic in Massachusetts, is found sporadically throughout the state, most frequently during summer months.

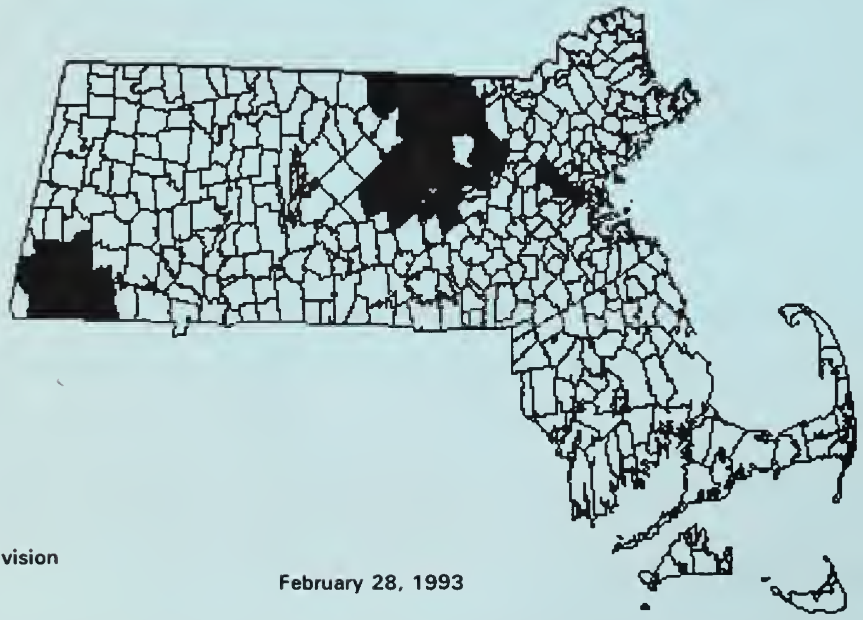
The work load has increased dramatically (Figure 1). In calendar 1992, the laboratory tested almost 1,100 animals compared to less than 400 in 1991. The laboratory accepts for testing the heads of animals involved in human or domestic animal exposure. In addition, to determine the extent of the spread of the raccoon rabies strain, the laboratory will also test sick and strangely acting raccoons, whether or not there has been an exposure, if the presence of virus has not yet been confirmed in a town.

Animals Submitted for Rabies Virus Testing
January 1990 - February 1993



Virology Division
Mass. State Laboratory Institute
Mass. DPH

Mid-Atlantic Raccoon Strain of Rabies Virus in Massachusetts



Virology Division
Mass DPH

February 28, 1993

CLIA '88
Highlights from the Technical Correction Notice

The following major highlights were taken from the Technical Correction Notice to the Clinical Laboratory Improvements (CLIA) which were published in the Federal Register on Tuesday, January 19, 1993;

o **Addition to the lists of waived tests includes;**
Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout (i.e., Hemoglobin by HemoCue)

o **New Category "Physician performed microscopy procedures";**
A laboratory may qualify to perform tests under this provision if it restricts physician-performed microscopy examinations to one or more of the following procedures, waived tests **and no others:**

(1) Wet mounts, including preparations of vaginal, cervical or skin specimens

(2) All potassium hydroxide (KOH) preparations;

(3) Pinworm examinations;

(4) Fern tests;

(5) Post-coital direct qualitative examinations of vaginal or cervical mucous; and

(6) Urine sediment examinations

Any procedure listed above under "Physician performed microscopy procedures "must be personally performed by a physician during the patient visit on a specimen from his or her own patient or from a patient of a group medical practice of which the physician is a member. For purposes of this category a physician will include Doctors of Podiatry and Osteopathy.

These procedures are categorized as moderately complex and are **not** waived from meeting the applicable CLIA requirements. Any laboratory qualifying under this category must register and obtain a CLIA certificate, participate in an approved proficiency testing program, if one is available and meet all of the applicable technical requirements under patient test management, quality control and quality assurance. In lieu of the personnel requirements in Subpart M, the laboratory must have a laboratory director who:

(A) Possesses a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required:

(B) Is a Doctor of Medicine, Osteopathy or Podiatry in the State in which the laboratory is located.

This category **exempts** a laboratory from routine inspection to determine compliance with the requirements; however it does not exempt the laboratory from complaint investigations when warranted.

A certificate for "physician performed microscopy procedures" is valid for no more than (2) years.

o **Personnel requirements have been revised to;**

- * recognize Podiatrists in the same categories as Doctors of Medicine and Osteopathy;
- * incorporate a provision to permit Dentists qualified in pathology to serve as laboratory directors and technical supervisors in the area of oral pathology
- * provide for the inclusion of individuals who passed the Health & Human Services (HHS) exam for technologists in 1987 to qualify as general supervisors;
- * allow individuals with a Bachelors degree in Cardiovascular Technology to qualify under the requirements for testing personnel and general supervisor in the area of blood gas analyses;
- * delay until further notice the effective date of the requirement for on-site supervision for those individuals with a minimum of a high school diploma to perform high complexity tests. This change would permit persons currently employed and performing high complexity testing to continue to work in the absence of on-site supervision, provided that the work performed during those times is checked by the general supervisor within twenty-four hours (24) or one working day.

Instructions for Changing CLIA Certificate Category

If you would like to change the type of certificate for the operation of your laboratory, use the following procedures:

(1) Change from Certificate of Registration to Certificate of Waiver

You have paid a certificate fee and have received a CLIA certificate of registration (a letter with the words "Certificate of Registration" across the top). You have determined that you now qualify for a certificate of waiver. Submit no payment, but return the CLIA User Fee Remittance Form, and the signed statement (B) enclosed. **To ensure proper accounting, you must include your CLIA ID Number on the signed statement.** If any additional fees are required, you will receive a corrected CLIA User Remittance Form. If you have overpaid, your account will be credited, and you will receive instructions for requesting a refund.

(2) Change from Certificate of Registration to Certificate of Physician-Performed Microscopy Procedures

You have paid a certificate fee and have received a CLIA certificate of registration (a letter with the words "Certificate of Registration" across the top). You have determined that you now qualify for a certificate for physician-performed microscopy procedures instead. Do not submit the amount indicated in "total due" but return the CLIA User Fee Remittance Form, and the signed statement (A) enclosed, and a payment of $50.00. **To insure proper accounting, you must include your CLIA ID Number on the signed statement and on the check.** If any additional fees are required, you will receive a corrected CLIA User Fee Remittance Form. If you have overpaid, your account will be credited, and you will receive instructions for requesting a refund.

If you have questions concerning the CLIA User Fee Remittance Form and Payment Coupon or the new requirements, call (410) 290-5850, (Monday through Friday 8AM - 5PM, EST). Recorded information is available anytime. You may also write to the following address.

HCFA CLIA Program
P.O. Box 26689
Baltimore, MD 21207-0489

CLIA Question of the Quarter

What Is A Fern Test?

Just what is this mysterious "fern test" that is included among the six tests categorized under "Physician-performed Microscopy?"

Is it some kind of exotic mycology procedure? Does it have anything to do with house plants?

Nope. The fern test is an ovulation test used by obstetricians/gynecologists to determine female fertility.

When cervical mucus is allowed to dry on slides it does so in a fern or palm-leaf pattern due to the formation of salt crystals resulting from the high concentrations of sodium chloride in the cervical mucus under the influence of estrogens. Progesterone tends to inhibit sodium chloride secretion in the cervical mucus, thereby decreasing the fern phenomenon.

* Reproduced with permission from the AAB UPDATE, Vol. 8, No. 3, February 1993, published by the American Association ofBioanalysts, Suite 918, 818 Olive Street, St. Louis, Missouri 63101, (314) 241-1445

From the Division of Health Care Quality

Policy Revisions for monitoring laboratory services under State Licensure

The new Federal requirements for laboratory services (CLIA '88), which became effective September 1, 1992, affect many health care providers licensed by the Department of Public Health. To minimize duplication between the State and Federal laboratory requirements, the Department has made changes to some of its policies for monitoring the performance of laboratory services. These changes became effective February 1, 1993.

For information regarding these changes or clarifications to the procedures for monitoring compliance with Massachusetts State licensure, call:

Kathleen Coyle
Division of Health Care Quality
(617) 727-5860, X343

STD Surveillance
Reporting STDs Invaluable to Disease Control Efforts

Reports of significant laboratory findings related to sexually transmitted diseases (STDs) are an invaluable tool for heightening disease surveillance and control efforts. Such findings, as mandated by MGL C111D, have dramatically increased the sensitivity of statewide surveillance, and has lead to improved disease control. Indeed, lab reporting is one factor that has enabled us to effect a dramatic decline in syphilis and gonorrhea in 1992.

Any laboratory that records a test result that suggests a current infection with syphilis, gonorrhea, chlamydia, or chancroid, is required to report that finding directly to the Health Department's Division of STD Control at 305 South St., Jamaica Plain, MA 02130. STD epidemiologist will contact the submitting physician to see if the lab finding is indicative of a diagnosed case. If you have any questions about this, please call Mr. George Coman in the STD Surveillance Unit (617) 522-3700.

STD SURVEILLANCE

1. Morbidity: The following are (provisional) reported morbidity for Week 9 of 1993:

DISEASE	WK 9/93	WK 9/92	YTD 93	YTD 92
Syphilis	18	28	207	215
Gonorrhea	70	67	573	692
Chancroid	0	0	0	0
GI	0	0	0	0
LGV	0	0	0	2
Chlamydia	204	157	1673	1785
Neonatal Herpes	0	0	0	0
PID	7	3	34	27

HUD Awards $9.5 Million to Commonwealth for Lead Paint Abatement Programs

The Department of Housing and Urban Development (HUD) awarded $44.4 million in grants to pay for the removal of lead-based paint in low- and moderate-income housing. The State of Massachusetts expects to receive a $6 million dollar grant and the City of Boston will get a separate grant of $3.5 million. HUD reported a total of ten grants were awarded nationally, from a field of 65 applicants.

The Executive Office of Communities and Development, in collaboration with the Department of Public Health's Lead Prevention Program, has developed a two-part comprehensive lead poisoning prevention strategy using new and existing resources.

The first step in the State's plan is the allocation of funds to cities and towns for neighborhood based demonstration projects aimed at the improvement of overall housing quality. The grant funds will be used strictly for lead abatement purposes, however additional resources will also be obtained to address larger underlying problems such as other code violations as well as adverse health and social issues which present impediments to successfully preventing lead poisoning. These neighborhood-based projects will receive approximately $2.5 million in grant funds. Another $500,000 will be given to one of two large resident-owned or non-profit-organization-owned housing developments for abatement work. The funds will be made available to those developments which serve low-income families and have no other forms of financial assistance are available.

The second major part of the strategy, often referred to as the "Gap Filler", is to leverage additional private resources and to make them accessible to those who cannot qualify for the existing financial assistance programs. The proposed strategy will expand eligibility to include both those who are considered "unbankable" and those who are considered too affluent for the existing programs.

EOCD estimates that there are about 1 million housing units in the Commonwealth containing some level of lead paint and about 4,000 of those units have very serious lead paint hazards. It is anticipated that the HUD grant will allow for the abatement of approximately 1800 housing units. If all 1800 were among the 4,000 worst properties in the Commonwealth, the grant would pay for the abatement of 45% of these hazardous dwellings.

If Massachusetts' systematic lead abatement strategy is successful, we will have made significant progress toward achieving the eradication of childhood lead poisoning.

National Laboratory Training Network

The Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) with support from the Centers for Disease Control (CDC), has established the National Laboratory Training Network (NLTN) to identify and address the Nation's high-priority laboratory training needs.

The NLTN consists of seven geographic areas or Area Laboratory Training Alliances (ALTA's). Each ALTA hosts an Area Resource Office (ARO) staffed by an Area Resource Director (ARD) and a CDC Training Advisor. They are available to answer any questions about the National Laboratory Training Network and to assist you in your laboratory training needs.

National Laboratory Training Network: New England ALTA NEWS

Good Laboratory Practices to Assist Laboratories in Meeting CLIA Regulations-A Guide for Laboratories Performing Moderately Complex Tests: The New England Area Resource Office of the National Laboratory Training Network and the New England State Public Health Laboratories have begun delivery of a modular workshop, developed with input by a network of expert representatives from public health laboratories, physician office laboratories, HCFA, state survey agencies, ASTPHLD and CDC. The first modules have begun in Vermont and Massachusetts, with additional modules being planned for all New England States. The series will be especially helpful for physician office laboratories, health clinics, and other non-hospital laboratories.

New England ALTA Calendar

Good Laboratory Practices Series (see above)

Module 1 - ½-day workshop: Procedure Manuals · Preventative Maintenance · Quality Control

April 27	Groton, CT	April 29	Stamford, CT
April 28	Hartford, CT	June 15	Concord, NH

Module 2 - ½-day workshop: Personnel & Facility Standards · Patient Test Management Requirements · QA · Lab Safety

May 11	Groton, CT	May 18	Stamford, CT
May 12	Hartford, CT	June 22	Concord, NH

Module 3 - ½-day workshop: Laboratory Methods & Techniques · Proficiency Testing · Laboratory Inspections

May 25	Groton, CT	June 2	Stamford, CT
May 26	Hartford, CT	June 29	Concord, NH

Identification of Medically Significant Fungi
2-day wet workshop, April 1-2, Randolph, VT

Identification of Clinically Significant "Moulds"
2-day wet workshop, April 17-18 Burlington, MA

Fluorescent Microscopy for MTB
1/2-day wet workshop, April 27, Concord, NH

Directing the Laboratory Performing Moderate Complexity Tests Quality Laboratory Management for Meeting CLIA'88 Requirements
Satellite Series awarding 20 CMEs, designed primarily for physicians practicing in the public health sector. Other clinicians who will find this course beneficial are welcome to participate.
June 9, 16, 23, sites to be determined throughout New England

Flow Cytometry Immunophenotyping Quality Assurance/Quality Control
3-day workshop, June 28-July 1, No. Dartmouth, MA

Upcoming Courses
Parasitology Workshops - Fall '93, MA and CT
Lead Methodology and Instrumentation - Fall '93, RI
TB: New Methods and Instrumentation - June '93, MA

For More Information: Please call the New England Area Resource Office (617) 522-3700 ext. 211, for information on these and other training programs offered in the region, and for a flier about the National Laboratory Training Network.

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